UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 27, 2002

MEMORANDUM

SUBJECT: Agency Response to Phase V Comments on Lindane

FROM: Mark T. Howard
Chemical Review Manager
Special Review Branch

TO: OPP Public Docket for Lindane (OPP Docket # 34239B)

This memorandum and its attachments address the public comments received during Phase 5 of the Public Participation Process which opened January 31, 2002 and closed April 1, 2002 (FR 67:4714-4716, January 31, 2002). During this phase, all interested parties were invited to participate and provide comments and suggestions on the ways the Agency might mitigate the estimated risks in the revised human health and ecological risk assessments.

Comments were received by the Natural Resources Defense Council (NRDC); Beyond Pesticides; World Wildlife Fund; Alaska Department of Environmental Conservation; Farm Workers Justice Fund, Inc.; National Pediculosis Association; Alaska Community Action on Toxics; Pesticide Action Network North America; the Attorney General of the State of New York; CA Regional Water Quality Control Board; Los Angeles County, CA Sanitation District; Thompson Family Farms Ltd.; Technology Sciences Group; Uniroyal Chemical Company, and a number of individuals.

Most of the comments received pertained to the Agency's methodologies and subsequent conclusions in assessing risks associated with the use of lindane for seed treatment. For instance, some commentors disagreed with the Agency's rationale for the reduction of the Food Quality Protection Act (FQPA) Safety Factor; disagreed also with the Agency's cancer classification for lindane; expressed concern regarding endocrine disruption from lindane, and the Agency not including breast milk exposure in the risk assessment; recommended that risk to workers from dermal and inhalation exposure to lindane should be combined; and noted that assessed surface water concentrations of lindane exceed current EPA Water Quality Standards. Information on modern seed treatment technology was also provided that helped refine occupational risks associated with commercial seed treatment.

The Agency also received comments regarding the pharmaceutical uses (i.e., lice and scabies treatments) of lindane. Comments received stressed the need for the Agency to assess and consider as part of the lindane RED the direct exposure from human application of these treatments, and the environmental and human health risk that result from the disposal of this compound to waste water treatment facilities following the lice and/or scabies treatment. In response, the Agency assessed, in cooperation with FDA, the risk associated with the direct application to humans of lindane pharmaceutical products for the treatment of lice and scabies. Further, the Agency assessed both human health and environmental risk from disposal of pharmaceutical products after application/use. EPA determined that when disposed to sewer systems, the concentration of lindane (using actual measured data from wastewater treatment plant outflows) was several orders of magnitude below the level that would raise a concern for environmental effects, or for human health effects if that water was used as a source of drinking water. Further details to similar comments can be found in Attachment C.

The Agency's response to Phase V comments on lindane are presented in three attachments: SRRD's Attachment A responds to general comments on risk assessments and risk management proposals. HED's Attachment B responds to comments on the revised human health risk assessment. EFED's Attachment C responds to comments on the revised environmental risk assessment.

1) Public Comments on incorporating lice and scabies treatment into EPA's Human Health Risk Assessment.

Numerous commentors stated that EPA's risk assessment of lindane would be incomplete without the inclusion of the pharmaceutical use of lindane as a lice and scabies treatment. Most of the commentors were aware that FDA (Food Drug Administration) regulates this use.[1] [2] The commentors frequently cited the Food Quality Protection Act (FQPA) and its mandate that EPA aggregate[3] the risks from all human exposures to a chemical as a requirement for consideration in the Reregistration Eligibility Decision (RED) of lindane. Most commentors requested the rules (i.e., the US Code of Federal Regulations) be amended so that EPA could work together with FDA on the assessment of aggregate risk of lindane use.

1) Response:

The Agency acknowledges the concern for the pharmaceutical use of lindane and has included an assessment for this exposure in its revised human health risk assessment. EPA and FDA collaborated in the examination of available data to assess the potential for lindane pharmaceuticals to cause adverse effects. This assessment lead to the EPA and FDA conclusion that use of lindane for head lice control in accordance with label directions does not pose risks of concern. The limited information available on the scabies product, however, suggests that there is some possibility a portion of the patient population using lindane for scabies control may experience adverse effects. FDA has concluded that, by limiting the potential to cause adverse effects through stronger warnings, clearer use directions, and other measures, the therapeutic benefits of lindane pharmaceutical products for scabies control outweigh the limited potential to cause adverse effects in the patient population. However, the Agency cannot conclude with reasonable certainty that exposure to lindane through scabies treatment will not result in unacceptable exposure and risk.

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[1]Under FFDCA (The Federal Food, Drug, and Cosmetic Act), FDA approves and enforces the use of pesticides for human ectoparasites (which includes lice and scabies).

[2]At its creation in 1970, the Environmental Protection Agency initially regulated the use of pharmaceuticals/pesticides on humans until a MOU was signed between EPA and FDA 1973 ceding that responsibility to FDA. This was later codified in the Code of Federal Regulations (see 40 CFR §152.20). The basis for the Agency's action was to avoid a redundant review of the safety of human applied pharmaceuticals containing pesticides.

[3]The terms aggregate and cumulative risk assessments have been the source of confusion to the public in regards to FQPA. An "aggregate" risk assessment under FQPA would look at the risk from one chemical from all exposure pathways for all uses of a chemical whereas a "cumulative" risk assessment would look at the risk collectively from similar chemicals expected to cause the same type of health effect in humans. Commentors typically asked for a cumulative risk to include lice and scabies treatments (FDA regulated uses) when they meant aggregate uses.

The existence of pharmaceutical sources of exposure to lindane raise questions of public policy and statutory interpretation that have not been resolved. These questions include: whether "aggregate exposure" encompasses exposures resulting from the use of lindane in pharmaceutical products; and if so, whether there is any reasonable statutory interpretation that could avoid apparently questionable public policy results. EPA is particularly concerned that the statute be interpreted and applied in a manner that yields results that are protective of public health and consistent with common sense. If sec. 408 of FFDCA were interpreted to cover exposure from pharmaceutical uses, then EPA might never be able to establish new tolerances, or to leave existing tolerances in effect, for a substance that is used both as a pesticide and a pharmaceutical product, if the pharmaceutical product caused adverse effects in humans. This result could occur regardless of the level of risk posed by the exposures permitted under the tolerance(s) and their associated pesticide registrations, and even though the pharmaceutical product has been deemed "safe and effective". In other words, EPA would be concerned about relying on an interpretation of FFDCA sec. 408 that could compel regulatory actions which would have no impact on the major source of exposure, and where the source of such exposure is fully regulated and approved under a public health standard. EPA is considering whether the statute requires the Agency to include in its safety assessment those exposures resulting from the use of lindane in pharmaceutical products.

EPA invites additional public comment on the regulatory and public policy questions raised by the use of chemicals, such as lindane, both as pesticides and pharmaceuticals.

Further information on FDA and how it regulates lindane can be obtained from its website: www.fda.gov; e.g., http://www.fda.gov/bbs/topics/ANSWERS/ANS00725.html.

2) Public Comment on disposal of lindane from lice treatments.

Several commentors also expressed concern about the potential human health and environmental impacts from the disposal of lice and scabies treatments. These treatments are rinsed off (disposed of) into municipal sewers that do not effectively remove lindane before discharging their effluent to surface waters.

2) Response

The Agency acknowledges the concern of the potential for lindane to contaminate surface waters after disposal in municipal sewer systems, including some surface waters that are used for drinking water and has included an assessment for this exposure in its revised human health risk assessment. The Agency used an exposure model and reported lindane concentrations in discharged effluent (0.03 ppb) from the Publically Owned Treatment Works (POTWs) of Sanitation Districts of Los Angeles County, California to assess the risks associated with estimated concentrations of lindane in surface water from consumer use for both lice and scabies treatments. The Agency did not identify any risk concerns for concentrations of lindane in surface water used as a source of drinking water.

3) Public comment on the use of Agency water quality standards in pesticide risk assessments.

The CA Regional Water Quality Control Board raised a concern that the Office of Pesticide Programs (OPP) lindane RED will not take into account the Water Quality Standard (WQS) for lindane that is set by EPA's Office of Water (OW), and that the lindane RED will not take into account all major sources (uses) of lindane in its environmental assessment (i.e., head lice and scabies treatment).

3) Response

Several municipal sanitation districts in California, most notably the LA County Sanitation District, have found mean concentrations of lindane in their wastewater effluent in the 10 - 40 parts per trillion (ppt) range. OW has a current water quality criterion (WQC) of 19 ppt for lindane in waters that is a source of both drinking water and aquatic organism consumption. OW has established a higher criterion of 63 ppt for waters used for aquatic organism consumption alone. The 19 ppt criterion was promulgated for CA by U.S. EPA as an enforceable standard as part of the CA Toxics Rule (CTR). Sanitation districts are concerned that their effluent has the potential to violate the CTR in cases when the wastewater treatment facilities discharge into streams where there is little or no receiving stream flow, such as in the southwestern part of the US.

The WQS established by OW is based on a 1980 cancer assessment that classified lindane as a B2/C carcinogen. As part of the lindane RED, OPP has reclassified lindane's carcinogenic potential using a recent lindane cancer study and a review of the all previous lindane cancer studies. In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July 1999), the OPP classified lindane as "Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." Similarly, when setting the maximum contaminant level goal (MCLG) for drinking water in 1991, OW concluded that, "there is inadequate evidence to state whether or not lindane has the potential to cause cancer from lifetime exposures in drinking water."

OW requires states to revisit their WQSs every 3 years. As part of this process, there is a possibility that the WQS and/or the WQC could change. The assessments completed for both the lindane RED which is based on the revised cancer classification, and the Office of Water's 1991 MCLG which is not based on the new draft guidelines but uses the1986 cancer classification scheme, will likely be considered in a re-evaluation of WQSs by states and/or the WQC by USEPA as necessary. OW is also required to revisit or re-evaluate existing National Primary Drinking Water Regulations (MCLs/MCLGs) every six years. Although it is not certain whether changes to a states' WQS for lindane will occur, recent information suggests that the WQS could be increased.

ATTACHMENT B

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 25, 2002

MEMORANDUM

SUBJECT: **Lindane**; Chemical No. 009001. HED's Response to Public Comment on HED's Revised Risk Assessment for Lindane Registration Eligibility Document (RED)

DP Barcode: D282320
Reregistration Case #: 0315

FROM: Becky Daiss, Environmental Health Scientist
Reregistration Branch 4
Health Effects Division (7509C)

THROUGH: Susan Hummel, Branch Senior Scientist
Reregistration Branch 4
Health Effects Division (7509C)

TO: Mark Howard, Chemical Review Manager
Reregistration Branch 3
Special Review & Reregistration Division (7508C)

This provides the Health Effects Division's (HED) response to comments from the public on EPA's January 30, 2002 Revised Human Health Risk Assessment for Lindane (gamma-hexachlorocyclohexane). Comments were received from the following organizations: Natural Resources Defense Council (NRDC); Beyond Pesticides; World Wildlife Fund (WWF); ; Alaska Department of Environmental Conservation, Farm Workers Justice Fund, Inc., National Pediculosis Association (NPD), Alaska Community Action on Toxics; Pesticide Action Network North America (PANNA); the Attorney General of the State of New York; Thompson Family Farms Ltd, Technology Sciences Group, Uniroyal Chemical Company, and a number of

individuals. A summary of the comments followed by HED's response is provided below. Suhair Shallal provided responses to comments pertaining to the toxicology assessment, Thurston Morton provided responses to comments on the residue chemistry and dietary assessments, David Jaquith responded to comments on the occupational exposure assessment, and Becky Daiss responded to general risk assessment comments.

Comments on the Toxicology Assessment

Public Comment: Several commenters reiterated their disagreement with EPA's rationale for reduction of the FQPA-mandated tenfold safety factor.

HED Response: Pursuant to the requirements set forth by FQPA (i.e. "on the basis of reliable data, such [smaller] margin will be safe for infants and children."), the Agency has reviewed the data and found that the reduced margin of 3X is safe for infants and children. The Agency's rationale behind reducing the Safety Factor (SF) is as follows: 1) In the case of lindane, the database to assess the increased susceptibility under the FQPA is complete. These studies include prenatal developmental studies in rats and rabbits; a reproduction study in rats, acute and subchronic toxicity studies in rats, and a developmental neurotoxicity study in rats. Therefore, as far as assessment under the FQPA is concerned the database is complete. 2) The reproductive and developmental toxicity studies submitted by the registrant, and those from the published literature and International Program for Chemical Safety report, do not show strong evidence of increased susceptibility. The reproduction and developmental toxicity studies in rats submitted by the registrant show effects on fetuses at or above the doses that causes parental or maternal toxicity; however, there appears to be a qualitative difference in the severity of effects on fetuses versus maternal animals in the reproduction study. The developmental neurotoxicity study (DNT) is the only study which shows a quantitative increase in the susceptibility of infants since the effects occur at a dose that dose not cause toxicity to maternal animals, and the effects seen are the same effects as in the reproduction study and, therefore, are confirmatory.

Public Comment: Commenters again stated that EPA had failed to properly assess endocrine disruption.

HED Response: There are concerns that lindane may be an endocrine disruptor (ED), however there are no requirements for studies that address these effects at this time. EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide

chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, lindane may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. Although the 1996 guidelines for reproduction study included several parameters to assess endocrine effects, the available reproduction study was conducted according to pre-1996 guidelines. Until appropriate screens and assays to assess the endocrine disrupting effects are developed, the FQPA Safety Factor will be determined based on susceptibility of infants and children to lindane exposure in standard toxicity tests.

Public Comment: Commenters once more stated that EPA failed to conduct a cumulative risk assessment for pesticides with a common mechanism of toxicity.

HED Response: OPP considers possible cumulative effects of a pesticide with other chemicals only if these chemicals share a common mechanism of toxicity. For example, OPP is currently considering cumulative effects of organophosphrous pesticides since they cause neurotoxic effects by cholinesterase inhibition. The Agency is still developing methods to assess cumulative (additive) effects of chemicals with a common mechanism of toxicity. If HED identifies other substances that share a common mechanism of toxicity with lindane, we will conduct a cumulative risk assessment once the final guidance for conducting cumulative risk assessments is available.

Public Comment: The World Wildlife Federation commented that EPA is incorrect in asserting that; 1) that the toxicology data base is complete, 2) the available data provide no indication of increased susceptibility in rats from in utero exposure to lindane in the prenatal development study, and 3) the offspring effects seen in the developmental neurotoxicity study were the same as those seen in the two-generation reproduction study (no additional functional or morphological hazards to the nervous system were noted).

HED Response: EPA considers the database to assess increased susceptibility under the FQPA to be complete. These studies include prenatal developmental studies in rats and rabbits; a reproduction study in rats, acute and subchronic toxicity studies in rats and delayed neurotoxicity in the hen, and a developmental neurotoxicity (DNT) study in rats. Therefore, as far as assessment under the FQPA is concerned the database is complete. The developmental toxicity study was only **one of three** studies that were used in assessing the appropriate safety factor to be applied to Lindane. The developmental toxicity study was **not** used as the **sole basis** for any part (oral, dermal, inhalation) of the Lindane risk assessment, including establishing the FQPA safety factor. The reproductive and developmental toxicity studies, both submitted by the registrant and those from the published literature and IPCS report, do not show strong evidence of increased

susceptibility. The reproduction and developmental toxicity studies in rats submitted by the registrant show effects on fetuses at or above the dose that causes parental or maternal toxicity; however, there appears to be a qualitative difference in the severity of effects on fetuses versus maternal animals in the reproduction study. The developmental neurotoxicity study (DNT) is the only study which shows a quantitative increase in the susceptibility of infants since the effects occur at a dose that dose not cause toxicity to maternal animals, and the effects seen are the same effects (decreased viability of offspring) as in the reproduction study and, therefore, are confirmatory. The NOAEL based on the effects seen in the DNT study (1.2 mg/kg/day) will be somewhat more protective than the NOAEL based on effects seen in the reproductive toxicity study (1.7 mg/kg/day).

Public Comment: Several commenters reiterated disagreement with OPP's current policy on use of human test data.

HED Response: The OPP has used human studies to select endpoints for risk assessment in the past. However, current Agency policy is that a regulatory decision cannot be made based on a human endpoint until a final policy regarding the ethical aspect of the use of human studies for regulatory purposes is issued. This approach was approved by the FIFRA Scientific Advisory Panel (SAP). The Agency is currently assessing the use of human studies to select endpoints for risk assessment. Therefore, for the lindane assessment, HED relied solely on animal data.

Public Comment: An number of commenters reiterated concerns regarding EPA's failure to include breast milk exposures in the risk assessment.

HED Response: EPA does not have current information on lindane levels in breast milk. However, the reproductive and developmental neurotoxicity studies include exposure to nursing infants. There was susceptibility seen in these studies and EPA has accounted for this with and FQPA factor of 3X. Therefore, we believe that the FQPA Safety Factor of 3X will be sufficiently protective of nursing infants.

Public Comment: Commenters again expressed disagreement with HED's cancer classification for lindane.

HED Response: A new carcinogenicity study in mice was submitted in January 2001. The OPP/Cancer Assessment Review Committee (CARC) has completed the review of the newly submitted carcinogenicity study in CD-1 mice along with other data. In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July, 1999), the CARC has classified lindane into the category **"Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential"** based on an increased incidence of benign lung tumors in female mice only. The Committee, therefore, recommended that the quantification of human cancer risk is not required. Although some epidemiologic data links α- or β-HCH to various types of cancer,

usually it is not lindane (γ-HCH). Some studies do refer to the γ-isomer; however, the contribution of other chemicals and their interactions with lindane is impossible to discern.

Comments on the Chemistry Chapter and Dietary Assessment

Public Comment: Technology Sciences Group Inc., on behalf of Uniroyal Chemical Company, noted that EPA rejected TSG's previous comments regarding the need for a new plant metabolism study and provided a more detailed discussion of why they believe that such a study would provide no new information. TSG also again requested that HED revise its chemistry chapter to include product chemistry data which was submitted by the registrant but did not appear in the chemistry chapter

HED Response: HED has reconsidered the plant metabolism issue based on the TSG's comment but our position regarding the need for a new plant metabolism study has not changed. Regarding outstanding product chemistry data, as stated in our previous comment response, once the product chemistry data is reviewed, a memorandum will be sent to the registrant listing HED's conclusions and listing any additional data required.

Public Comment: Commenters again stated that previous uses of lindane should be assessed in the dietary exposure analysis. PANNA noted that the Food and Drug Administration's Total Diet Study provides information on residues in mor than 40 food products.

HED Response: HED does not conduct dietary assessments incorporating past uses of a chemical which are now canceled and for which tolerances have been recommended for revocation. In addition, the USDA Pesticide Data Program (PDP) has analyzed over 20,000 samples of vegetables, fruit, milk, and grains from 1997 to 1999 and there were only 5 detections of lindane (maximum residue of 0.031 ppm). The FDA Total Diet Study included sampling years prior to the cancellation of some lindane uses. Also, the Total Diet Study does not contain a sufficient number of samples for use in dietary exposure analyses.

Public Comment: Commenters again argued that the beta isomer of hexachlorocyclohexane (HCH) should be assessed in the dietary exposure analysis also, due to the transformation of lindane (which is the gamma isomer of HCH) to beta hexachlorocyclohexane.

HED Response: As noted in our previous response to comment, HED believes the available data do not support significant isomerization of lindane (gamma-HCH) to beta-HCH in the environment. Therefore, HED will not include beta hexachlorocyclohexane in the dietary exposure assessment.

Comments on the Worker Exposure Assessment

Public Comment: Uniroyal and TSG reviewed assumptions used for HED's worker exposure and submitted a reassessment of worker exposures from commercial seed treatment. Thompson Family Farms Ltd urged EPA to consider information regarding modern seed treatment technology.

HED Response: HED has reevaluated the estimates of exposure and risk from commercial treatment of wheat and canola seed with lindane using data from a more recent study measuring exposures of workers treating canola seed with HELIX 289S (a mixture of thiomethoxam, difenoconazole, metalaxyl, and fludioxonil). A detailed description of the revised analysis is provided an April 23, 2002 memorandum from D. Jaquith (D282419). HED has also reevaluated the exposure estimates for the planting of seed treated with lindane. These revisions are based on data provided in a study measuring exposures of workers planting seed treated with isophenphos. Details of the revised planting assessment are provided in an April 24, 2002 memorandum from D. Jaquith. ~~(D282637)~~ [SRRD Technical Correction: The reference for the D. Jaquith review memorandum dated April 24, 2002 is D282418.]

Comments on the Risk Assessment

Public Comment: A number of commenters reiterated that HED should combine risk to workers from dermal and inhalation exposure to lindane.

HED Response: Our previous response to this comment stated that HED does not, as a matter of policy, aggregate risk from dermal and inhalation exposures unless there is a common toxicological endpoint for each route of exposure. However, HED believes commenters have raised a valid concern given the observed effects at the recommended NOAELs for lindane for each of these pathways. Therefore, HED will review existing policy regarding addition of risks from difference exposure routes based on toxicological endpoints. HED will not aggregate these exposures for the lindane risk assessment, however, since addition of dermal and inhalation exposure will not change the overall results of the occupational exposure assessment.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EFED response to PHASE V public comments regarding the DRAFT EFED RED chapter for **Lindane.** PC Code No. 009001; DP Barcode: D282320

TO: B. Shackleford, Branch Chief
M. T. Howard, Team Leader
Special Review and Reregistration Division (7508C)

FROM: N.E. Federoff, Wildlife Biologist, Team Leader
J. Melendez, Chemist
F. Khan, Environmental Scientist, Water Resource Assessor
Environmental Risk Branch V
Environmental Fate and Effects Division (7507C)

APPROVED BY: Mah T. Shamim, Ph.D., Chief
Environmental Risk Branch V
Environmental Fate and Effects Division (7507C)

Lindane Docket Control No. OPP-34239B

COMMENT 11: Torsten Brinch: EFED would be interested in reviewing the information, however no citation nor data were provided with the comment.

COMMENT 13: Comments from The National Resources Defense Council:

Failure to include topical use of lindane for lice and scabies: Recently, EFED calculated the estimated concentrations of lindane in surface water used as a source of drinking water from consumer use for both lice and scabies treatments. . Surface water concentrations were based on the reported lindane concentration of discharged effluent from the Publically Owned Treatment Works (POTWs) of Sanitation Districts of Los Angeles County.

Exposures are further based on the effects of treatment in a Publically Owned Treatment Works (POTW). The EFED does not possess a method nor has it traditionally conducted exposure assessments for the released of pesticides to domestic wastewater from consumer uses. Therefore, EFED obtained and relied on the Office of Pollution Prevention and Toxics'(OPPT) consumer exposure model, Exposure and Fate Assessment Screening Tool (E-FAST) to estimate lindane concentrations in surface water. Specifically, EFED used the submodel's equations designed for releases to domestic wastewater treatment, often referred to as Down-the-Drain Releases.

In absence of specific data for the submodel (i.e., daily per capita release of chemical to a wastewater treatment facility, daily per capita wastewater volume released, and fraction of chemical removed during wastewater treatment), the calculated average concentration of effluents from waste water treatments was used as surrogate. It is assumed that the factors (i.e., daily per capita release of chemical to a wastewater treatment facility, daily per capita wastewater volume released, and fraction of chemical removed during wastewater treatment) of the submodel are accounted for the reported concentrations of the discharged effluents from the POTWs of Los Angeles Sanitation Districts. EFED assumes that the reported concentrations of lindane from wastewater treatment were discharged and instantaneously diluted into surface water where no further removal (e.g., degradation, adsorption, volatilization) occurs. Stream dilution, referred to as Stream Dilution Factor, is equal to the volume of receiving stream flow under specific flow conditions divided by the volume of wastewater released from the POTW. The resulting concentration is then used for estimating drinking water concentrations in the human health risk assessment. Based on instantaneous and upper-end SDF dilution factors, EFED may have used conservative approach to estimate the acute and chronic concentrations.

CA Utility:
Failure to use the Office of Water's 19 ppt lindane standard for surface water bodies: SRRD, HED, and EFED have contacted Office of Water to resolve the inconsistences of lindane standards in the surface water bodies.

COMMENT 19: The Technology Sciences Group Inc.:

Supported Uses of Lindane have decreased: EFED acknowledges these corrections and the revised RED will reflect these changes.

The registrant indicates that the models FIRST and GENEEC2 are not appropriate for lindane because the chemical is volatile: EFED uses a tiered system of pesticide exposure modeling to assess risk of a pesticidal product to the environment. Each of the tiers is designed to screen out pesticides by requiring higher, more complex levels of investigation only for those that have not passed the next lower tier. EFED recognizes that the Tier I models use limited fate parameters, and may have overestimated the Estimated Environmental Concentrations (EECs) in surface waters. However, to our knowledge, none of the EECs exceeded the Drinking Water Level of Concern (DWLOCs). Therefore, no further refinements were necessitated for lindane. In addition, as stated previously, aquatic risks were calculated with the assumption that 100% of the compound disassociates from the seed surface. These risks may be highly conservative due to this assumption. Thus, the Agency is requiring a seed leaching study to further characterize possible exposure.

Use of Monitoring Data: The registrant agrees with all the comments from EFED about why the monitoring data available cannot be used to estimate drinking water concentrations, but they object the expression that the detections in ground and surface waters may be due to prior agricultural uses: EFED acknowledges that the use of lindane has decreased substantially in recent years. However, Several studies, reported as recently as 2001, indicate that there are still detections of lindane in various compartments of the environment. Again, EFED encourages the registrant to further evaluate the correlation between known lindane use and the occurrence data available through the monitoring sources. Information such as, but not limited to; the timing of lindane application; proximity to the sampling site; and proximity of sampling site to the nearest drinking water intake are necessary to better characterize the usefulness of the monitoring data.

The registrant objects to the identification of pentachlorocyclohexane as a possible degradate of lindane: The referenced sentence is the last one of the first paragraph in the Summary of the ENVIRONMENTAL FATE AND TRANSPORT ASSESSMENT. The sentence reads as follows: "Possible degradates could include isomers of pentachlorocyclohexane, 1,2,4,-trichlorobenzene, and 1,2,3-trichlorobenzene." EFED acknowledges that there is a typographical error and that the word pentachlorocyclohex**a**ne should be substituted to pentachlorocyclohex**e**ne.

COMMENT 21: Los Angeles County (CA) Sanitation District, James Stahl, Paul Martyn, Industrial Waste Section:

Primary concern is that the Agency's assessment is deficient and fails to take into account the environmental risk associated with the use of lindane in lice and scabies treatment: EFED agrees that lice and scabies treatment may affect risk. An assessment of risk has now been included (see D282004 memorandum of 4/25/02) regarding releases of lindane into the environment from uses other than seed treatment (e.g., use of lindane to treat head lice or scabies). Estimated surface water concentrations are **acute = 0.0004 ppb** based on a high-end stream dilution factor (i.e., upper 10^{th} percentile) and **chronic = 0.00003 ppb** based on the median stream dilution factor (i.e., 50^{th} percentile).

The County Sanitation Districts of Los Angeles County is also concerned that risks to aquatic organisms will be "more severe" when lice and scabies treatments are also considered: The aquatic assessment was based on the assumption that 100% of the compound disassociates from the seed surface. These risks may be highly conservative and unrealistic due to this assumption. Thus, the Agency is requiring a seed leaching study to further characterize possible exposure. The addition of the lice and scabies treatments may increase risk to an extent, but due to the uncertainty associated with the aquatic assessment and the likely highly conservative and unrealistic conclusions, this increase may be negligible overall (as noted above, estimated surface water concentrations are **acute = 0.0004 ppb and chronic = 0.00003 ppb**).